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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/016,159 01/30/98 LEE

J 07004 002002
EXAMINER

HM12/0614

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ART UNIT PAPER NUMBER
FITZGERALD, D.

DATE MAILED: 1646

06/14/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 26 March 1989

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-7 is/are pending in the application.
Of the above, claim(s) 1, 2, 4, 6, 7 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 3, 5 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-7 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

BEST AVAILABLE COPY

1. The computer-readable sequence listing filed 19 January 1999 satisfies the requirement therefor.

In view of applicant's amendment of the § 120 priority claim and the claims, the rejections under 35 U.S.C. §§ 102(b) and 103(a) set forth in the last Office action (¶¶ 6 and 7 of the Office action mailed 09 December 1998, Paper No. 4) are withdrawn in favor of new rejections set forth below.

Insofar as the arguments advanced in the reply filed 26 March 1999 apply to the new rejections below, they have been fully considered but are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3 and 5 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the invention as now claimed. This is a new matter rejection.

The specification as filed does not support the recitation of unglycosylated EPO receptor polypeptides. The subgenus of such unglycosylated receptors is not necessarily the same as any of the subgenera which are described in the specification. It would be possible, for example, to produce the specified polypeptides in expression systems not capable of glycosylating them but yet capable of effecting other posttranslational modifications. Applicant argues that one of ordinary skill in the art would have found it obvious that the *E. coli* expression products described in the specification are unglycosylated. This argument is not persuasive because "[o]ne shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997), citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991).

4. Claims 3 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Harris *et al.* (*JBC* 267: 15205-09, 1992).

Harris describes the production of an unglycosylated hEPO-R polypeptide, an "EREx" fusion produced in *E. coli* and that it binds to immobilized hEPO (abstract). The reference also describes immobilization of the EREx polypeptide on glutathione-agarose beads, *i.e.*, a solid-phase matrix, and the use of the immobilized receptors for binding assays (*id.*). It reasonably appears that the prior art EREx polypeptide meets the limitation of "consisting essentially of" the extracellular domain of the EPO receptor, and it further reasonably appears that notwithstanding its use for binding assays which do not employ an immunochemical reagent, the GSH-agarose-immobilized EREx polypeptide meets all of the material and functional limitations of the "immunoassay reagent" of claim 5.

5. Claims 4, 6, and 8 rejected under 35 U.S.C. § 103(a) as being unpatentable over Harris (*JBC*, 1992) in view of D'Andrea *et al.* (U.S. Patent No. 5,378,808).

The relevant teachings of Harris are as discussed above, and those of D'Andrea, at ¶¶ 6 and 7 of Paper No. 4. Harris does not describe the production of a polypeptide consisting of only the extracellular domain of hEPO-R as an immunogen, nor does it describe solid-phase assays employing the antibodies it discloses.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a secreted receptor polypeptide according to the teachings of D'Andrea, using an *E. coli* expression system, as described by Harris, because the artisan would reasonably have expected such a polypeptide to have the EPO-binding properties of the EREx fusion protein as described by Harris and to be useful for any of the other purposes described in the '808 patent. It further would have been obvious to employ the bacterial polypeptide as an EPO-capture reagent in a conventional immunoassay as was known in the art, *e.g.*, an ELISA, thus to practice the invention of claim 5, because Harris teaches that the similar EREx polypeptide is useful for that purpose. The claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

6. The examiner believes that he has addressed all pertinent arguments. No claim is allowed.

7. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED. ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(A) WOULD THEN BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

8. Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

Telephone (703) 308-3934

Fax

All formal papers (703) 308-4242

Informal communications (703) 308-0294

e-mail (note PTO policies below) david.fitzgerald@uspto.gov

Inquiries of a general nature should be directed to the Technology Center 1 receptionists at (703) 308-0196.



DAVID L. FITZGERALD
PRIMARY EXAMINER
ART UNIT 1646

11 June 1999

The best time to reach Examiner Fitzgerald is from 9 a.m. to 4 p.m. (Eastern). If he cannot take a call, a message may be left on his voicemail. Should attempts to reach him be unsuccessful, the acting supervisor for this Art Unit, Paula Hutzell, may be reached at (703) 308-4310.

Most official papers and all informal **communications may be submitted to the PTO by fax**. For specific policies, refer to 37 C.F.R. § 1.6 and the notice published at 1096 O.G. 30. To facilitate their receipt and handling, please —

- ♦ Call the examiner when you send an urgent communication.
- ♦ **Do not send a duplicate copy by mail or courier.**

Any Internet e-mail communications will be made of record in the application file. PTO employees cannot engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. § 122. This policy is more fully set forth in the Interim Internet Usage Policy published in the PTO's *Official Gazette* on 25 February 1997 at 1195 O.G. 89.